

MAR 24 2005

Mr. John Morley
President
Natural Factors Nutritional Products, Inc.
111 80th Street S.W.
Suite 100
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letter of February 15, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **RxOmega-3 Factors Fish & Flax Oil EPA 400mg/DHA 200 mg/ALA 530 mg** is using the claim "[P]roviding the essential fatty acids EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease." This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it represents that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). In a September 8, 2004 letter in response to the court decision directing the FDA to consider qualified health claims for dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)) when the evidence in support of the claim does not meet the significant scientific agreement standard, we stated that FDA would exercise its enforcement discretion for a qualified claim with respect to omega-3 fatty acids and reduced risk of coronary heart disease (a copy of the letter can be found at <http://www.cfsan.fda.gov/~dms/ds-ltr38.html>)¹. In that letter, FDA stated that it will consider exercising enforcement discretion for the following qualified health claim:

Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

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¹You can find copies of the agency's October 31, 2000, February 16, 2001, and February 8, 2002 letters on omega-3 fatty acid qualified health claims at <http://www.cfsan.fda.gov/~dms/ds-lab1.html>.

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A dietary supplement bearing a claim that is not eligible to use the claim or that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(r)(1)(B) of the Act, a misbranded drug under section 502(f)(1), and as an unapproved new drug under section 505(a).

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA240

Natural Factors Nutritional Products Inc.

February 15, 2005

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Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: RxOmega-3 Factors™ Fish & Flax Oil EPA
400 mg/DHA 200 mg/ALA 530 mg

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Place
Burnaby, B.C.
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th Street SW, Suite 100
Everett, WA 98203

Text of Side Panel: RxOmega-3 Factors™ is a pharmaceutical grade liquid fish oil concentrate providing the essential fatty acids EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving (2 softgels) provides 400 mg of EPA and 200 mg of DHA omega-3 fatty acids. Stringent quality control standards ensure this highly purified fish oil concentrate is free from toxic environmental contaminants and heavy metals like mercury.

Text on PDP: Dr. Michael Murray Recommended Pharmaceutical Grade Fish Oil

Name of dietary ingredient that is the subject of statement Pharmaceutical Grade Fish Oil Concentrate (anchovy, sardine, mackerel), Omega-3 Fatty Acid (EPA, DHA) Organic Flaxseed Oil (ALA)

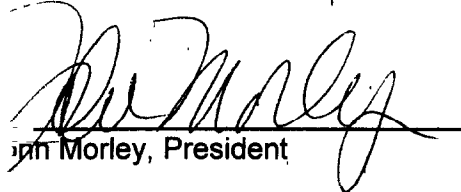
Name of the dietary supplement: Natural Factors

1111 80th Street S.W., Suite 100
Everett, WA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

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represent the information presented to be accurate and in compliance with supplement
bel regulations.


John Morley, President

2/15/05
Date